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JAN 25 2007

Remarks

The above-identified application has been carefully reviewed in light of the office action mailed on October 25, 2006. Applicant hereby respectfully requests reconsideration in view of the following remarks.

Claims 30-33 and 36-44 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel (U.S. Patent No. 5,591,187) in view of Sirimanne et al (U.S. Patent No. 6,136,014). Applicant traverses this rejection.

The present claims provide methods of removing material from a breast of a human or animal. The methods remove material from a breast less invasively and/or with reduced risk to the patient relative to many prior art devices and procedures.

Independent claim 30 is directed to such a method which comprises the steps of placing into a breast of a human or an animal a cannula having an open, distal tip and a rotational element disposed at least partially in the cannula, and rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open, distal tip of the cannula.

Dekel discloses a tissue removal device and method adapted to remove tissue from within the peritoneal cavity during laparoscopic surgery. Submitted herewith, as Attachment A, is a copy of a webpage from Wikipedia which provides a definition of laparoscopic surgery. As set forth in Attachment A, laparoscopic surgery refers only to operations within the abdomen and pelvic cavity. This is fully consistent with the disclosure in Dekel

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that the disclosed device is adapted to remove tissue from within the peritoneal region during laparoscopic surgery.

Dekel discloses using a corkscrew-like device which protrudes from a cylindrical sheath and is inserted into tissue to be retrieved from the peritoneal region. To retrieve tissue, the protruding corkscrew-like device is inserted into the tissue specimen outside of the sheath by a user manually twisting a T-handle located on a proximal end of the instrument. Once the corkscrew-like device has been mechanically inserted into the tissue specimen, the T-handle is then pulled in a proximal direction, thereby causing the peritoneal tissue to be pulled directly into the sheath.

Dekel does not disclose, teach or suggest the present invention. For example, Dekel does not disclose, teach or even suggest any method of removing material from a breast, let alone a method comprising placing into a breast a cannula having an open distal tip and a rotational element disposed at least partially in the cannula, and rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open distal tip of the cannula, as recited in the present claims. To the contrary, the clear, direct and express teaching of Dekel is that the methodology disclosed is adapted to remove tissue from the peritoneal region during laparoscopic surgery and mechanically pulls the tissue into the sheath. Thus, Dekel actually teaches away from any method of removing material from a breast, let alone the method of removing material from a breast as recited in the present claims.

Sirimanne et al discloses a device and procedures for removing integral volumes of tissue, such as breast tissue, via

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percutaneous access. Sirimanne et al discloses a RF, ultrasound or mechanical cutter functioning outside a tubular tissue removal member to cut a tissue segment from a body. A separate grasping tool, such as a hook or a pair of graspers, is then used to pull the cut, separated tissue into the lumen of the tubular tissue removal member. In an embodiment shown in Figs. 4a and 4b, the tissue cut from the body as described above is in a spiral form. A hook is used to pull the material into the tubular tissue removal member. A separate auger-like device is located in the lumen of the tubular tissue removal member and maintains the integrity and continuity of the cut, separated tissue.

Sirimanne et al does not disclose, teach or suggest the present invention, and does not supply the deficiencies apparent in the teachings of Dekel. For example, like Dekel, Sirimanne et al does not disclose, teach or even suggest a method of removing material from a breast comprising placing into a breast a cannula having an open distal end and a rotational element disposed at least partially in the cannula, and rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open distal end of the cannula, as recited in the present claims. Sirimanne et al discloses a method of removing tissue from a body which is substantially different from, and not in the least even suggestive of, the method of the presently claimed invention. For example, Sirimanne et al discloses that central to the disclosed invention is the concept that a separate cutting member, located outside the tubular tissue removal member, is used to cut an integral tissue sample. A further

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separate tissue manipulation device, such as a hook or a grasper, engages the cut tissue outside the tubular tissue removal member and pulls the tissue into and through the tubular tissue removal member.

In addition, one of ordinary skill in the art is provided with no motivation or incentive or has any other reasonable basis for combining the teachings of Sirimanne et al, involving different methodology than set forth in the present claims, with the peritoneal region-related teachings of Dekel for any purpose, let alone for the purpose of making obvious the present invention. Simply put, the teachings of both Dekel and Sirimanne et al are deficient with regard to the present claims and are so different and distinct one from the other that one of ordinary skill in the art has no basis for combining these references for any purpose, let alone for the purpose of making obvious the present invention. The references suggest no desirability or any other basis for combining their teachings to make obvious the present invention.

In view of the above, applicant submits that the present claims, and in particular claims 30-33 and 36-44, are unobvious from and patentable over Dekel in view of Sirimanne et al under 35 U.S.C. 103(a).

The Examiner has rejected claims 34 and 35 under 35 U.S.C. 103(a) as being unpatentable over Dekel and Sirimanne et al and further in view of Shiber, U.S. Patent No, 4,883,458. Applicant traverses this rejection.

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Shiber discloses an atherectomy catheter "useful for treating small arteries in the heart or brain... which requires a ...catheter having a diameter as small as 1 mm" (Shiber, column 7, lines 11-15).

Shiber does not disclose, teach or even suggest the present invention. For example, like Dekel and Sirimanne et al, Shiber does not disclose, teach or suggest a method for removing material from a breast comprising placing into a breast a cannula having an open distal end and a rotational element disposed at least partially in the cannula, and rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open distal tip of the cannula, as recited in the present claims.

The disclosures and deficiencies of the Dekel and Sirimanne et al references have been discussed previously and are resubmitted here.

Applicant submits that Shiber does not supply the deficiencies apparent in the previous combination of references. To a large extent, the Shiber reference has substantially the same deficiencies with regard to the present claims as do both Dekel and Sirimanne et al.

In addition, neither Dekel nor Shiber even remotely suggests anything regarding removing tissue from a breast, let alone the methods of removing material from a breast recited in the present claims. The methods disclosed in Dekel, Sirimanne et al and Shiber are so different and distinct, one from the other, that one of ordinary skill in the art would have no basis for using such different and distinct teachings to make obvious the present invention. In addition, the substantial, even

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dramatic differences between a peritoneal region, a blood vessel, and a breast are such that one of ordinary skill in the art would not even attempt to combine the deficient blood vessel-related teachings of Shiber and the deficient peritoneal region-related teachings of Dekel and the deficient breast tissue removal teachings of Sirimanne et al for any purpose, let alone for the purpose of making obvious the present methods, as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 34 and 35, are unobvious from and patentable over Dekel and Sirimanne et al in view of Shiber under 35 U.S.C. 103(a).

Claim 45 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Dekel and Sirimanne et al and further in view of Fox. Applicant traverses this rejection.

Fox discloses instrumentation for collecting bone cuttings.

Fox does not disclose, teach or even suggest the present invention, and does not supply the deficiencies apparent in the teachings of Dekel and Sirimanne et al. For example, like Dekel and Shiber, Fox does not disclose, teach or even suggest any methods of removing material from a breast, let alone a method comprising placing into a breast a cannula having an open distal tip and a rotational element disposed at least partially in the cannula and rotating the rotational element relative to the cannula, thereby at least assisting in drawing a material from the breast into the open distal tip of the cannula, as recited in the present claims.

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The Examiner states that Fox discloses a material collection system and a collection chamber structured to facilitate one of quantifying material removed from a breast and observing removed materials from the breast. However, as applicant has strenuously argued in the Response filed on October 16, 2006, Fox's teachings are so specific and limited to removal of material from hard structures, specifically bone, that one of ordinary skill in the art is provided with no motivation or other basis from Fox to extend the very limited teachings of Fox to encompass an operation for removing material from a soft breast. Thus, applicant respectfully submits that the Examiner's statement that Fox teaches a material collection system for breast material is substantially without merit.

The disclosures and deficiencies of the Dekel and Sirimanne et al references have been discussed previously and are resubmitted here.

The methods disclosed in Dekel, Sirimanne et al and Fox are so different and distinct, one from the other, that one of ordinary skill in the art would have no proper basis for combining such different teachings for any purpose, let alone to make obvious the present invention. In addition, the substantial, even dramatic differences between a bone, a peritoneal region, and a breast are such that one of ordinary skill in the art would not even attempt to combine the deficient bone-related teachings of Fox and the deficient peritoneal region-related teachings of Dekel and the deficient breast tissue removal teachings of Sirimanne et al for any purpose, let alone for the purpose of making obvious the present methods, as recited in the present claims.

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In view of the above, applicant submits that the present claims, and in particular claim 45, are unobvious from and patentable over Dekel and Sirimanne et al in view of Fox under 35 U.S.C. 103(a).

Further, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art, taken singly or in any combination, disclose, teach or even suggest the presently claimed methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

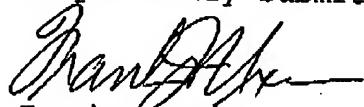
In conclusion, applicant has shown that the present claims are unobvious from and patentable over the prior art, including Dekel, Sirimanne et al, Shiber and Fox, and any combination thereof, under 35 U.S.C. 103(a). Therefore, applicant submits that the present claims, that is claims 30-45, are allowable and respectfully requests the Examiner to pass the above-identified application to issuance at an early date.

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Should any matters remain unresolved, applicant respectfully requests the Examiner to contact applicant's attorney at the telephone number given below.

Respectfully submitted,



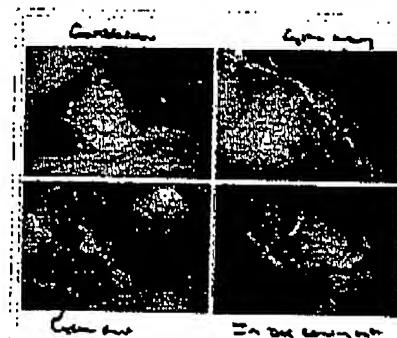
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Attachment A

# Laparoscopic surgery

From Wikipedia, the free encyclopedia

**Laparoscopic surgery**, also called *minimally invasive surgery* (MIS), *bandaid surgery*, or *keyhole surgery*, is a modern surgical technique in which operations in the abdomen (*Abdomen* is Latin for belly) are performed through small incisions (usually 0.5 - 1.5 cm) as compared to larger incisions needed in traditional surgical procedures. Medically, laparoscopic surgery refers only to operations within the abdomen or pelvic cavity. Laparoscopic surgery belongs to the field of endoscopy. The key element in laparoscopic surgery is the use of a laparoscope: a telescopic rod lens system, that is usually connected to a videocamera (single chip or three chip). Also attached is a fibre optic cable system connected to a 'cold' light source (halogen or xenon), to illuminate the operative field, inserted through a 5 mm or 10 mm canula to view the operative field. The abdomen is usually insufflated with carbon dioxide gas to create a working and viewing space. Additional 5-10 mm thin instruments can be introduced by the surgeon through trocars (hollow sheaths). Rather than a 20 cm incision as in traditional cholecystectomy, four incisions of 0.5-1.5 cm will be sufficient to perform a laparoscopic removal of a gallbladder.



Cholecystectomy as seen through a laparoscope

It is difficult to credit one individual with the pioneering of laparoscopic approach. In 1902 Georg Kelling of Dresden performed the first laparoscopic procedure in dogs and in 1910 Jacobaeus of Sweden reported the first laparoscopic operation in humans. In the ensuing several decades, numerous individuals refined and popularized the approach further for laparoscopy. It was not until 1985 when, with the advent of a new and specialized computer chip television camera, the approach was broadened in scope to include surgical resection of organs such as gall bladder. The first successful laparoscopic removal of gall bladder in humans was reported in 1987 in France. The introduction of computer chip television camera was a seminal event in the field of laparoscopy. This innovation in technology provided the means to project a magnified view of the operative field onto a monitor, and at the same time freed both the operating surgeon's hands, thereby facilitating performance of complex laparoscopic procedures. Prior to its conception, laparoscopy was a surgical approach with very limited application and used mainly for purposes of diagnosis and performance of simple procedures.

Conceptually, the laparoscopic approach is intended to minimise post-operative pain and speed up recovery times, while maintaining an enhanced visual field for surgeons. Due to improved patient outcomes, in the last two decades, laparoscopic surgery has been adopted by various surgical subspecialties including gastrointestinal surgery, gynaecologic surgery and urology. Based on numerous prospective randomized controlled trials, the approach has proven to be beneficial in reducing post-operative morbidities such as wound infections and incisional hernias (especially in morbidly obese patients), and is now deemed safe when applied to surgery for cancers such as cancer of colon.

The restricted vision, the difficulty in handling of the instruments (hand-eye coordination), the lack of tactile perception and the limited working area are factors which add to the technical complexity of this surgical approach. For these reasons, minimally invasive surgery has emerged as a highly competitive